

What is Claimed is:

1. A pharmaceutical composition comprising a statin cholesterol lowering agent and aspirin in a formulation designed to minimize statin:aspirin interaction.
- 5 2. The pharmaceutical composition as defined in Claim 1 wherein the statin and aspirin are formulated together in the same dosage formulation.
- 10 3. The pharmaceutical composition as defined in Claim 2 wherein the statin and aspirin are formulated together in a single tablet.
4. The pharmaceutical composition as defined in Claim 3 wherein the tablet is a bilayered tablet wherein the aspirin is present in a first layer, and the statin is present in a second layer.
- 15 5. The pharmaceutical composition as defined in Claim 4 wherein the layer containing the statin also includes one or more buffering agents.
6. The pharmaceutical composition as defined in Claim 3 wherein the tablet includes a core and a coating layer surrounding said core and wherein one of the statin and aspirin is present in the core and the other is present in the coating layer surrounding the core.
- 20 7. The pharmaceutical composition as defined in Claim 6 wherein the aspirin is present in the core and the statin is present in the coating layer.
- 25 8. The pharmaceutical composition as defined in Claim 7 wherein the coating layer also includes one or more buffering agents.
9. The pharmaceutical composition as defined in Claim 1 wherein the statin is pravastatin, lovastatin, simvastatin, fluvastatin, atorvastatin or cerivastatin.
- 30 10. The pharmaceutical composition as defined in Claim 1 further including one or more buffering agents in combination with the statin.
- 35 11. The pharmaceutical composition as defined in Claim 3 further including an outer protective coating or finishing layer surrounding said tablet.

12. The pharmaceutical composition as defined in
Claim 1 wherein the aspirin is in the form of enteric
coated aspirin granules.

13. The pharmaceutical composition as defined in
5 Claim 12 in the form of tablets or granules contained in a
capsule.

14. The pharmaceutical composition as defined in
Claim 12 wherein the enteric coated aspirin granules
include a finishing overcoat, and the coated aspirin and
10 statin are in the form of a tablet or capsule.

15. The pharmaceutical composition as defined in
Claim 14 wherein the coated aspirin granules and statin
granules are encapsulated separately into the same capsule
shells.

15 16. The pharmaceutical composition as defined in
Claim 2 wherein the aspirin is in the form of enteric
coated granules of aspirin and the statin is in the form of
enteric coated granules of statin, in the form of
compressed tablets or capsules.

20 17. The pharmaceutical composition as defined in
Claim 1 in the form of a tablet or capsule containing both
aspirin granules and statin granules.

18. The pharmaceutical composition as defined in
Claim 17 wherein the statin is in the form of enteric
25 coated statin granules.

19. The pharmaceutical composition as defined in
Claim 17 wherein the statin granules include an outer
protective coating to minimize interaction with aspirin.

20. The pharmaceutical composition as defined in
30 Claim 1 in the form of a bilayered tablet which comprises a
first layer comprising aspirin granules and one or more
excipients, and a second layer comprising a statin and one
or more buffering compounds and one or more excipients.

21. The pharmaceutical composition as defined in
35 Claim 20 wherein the first layer comprises aspirin
granules, one or more bulking agents and optionally a
lubricant, and the second layer comprises a statin,

optionally a wet granulating agent, one or more buffering compounds selected from the group consisting of calcium carbonate, magnesium oxide, magnesium carbonate and mixtures thereof, and optionally magnesium stearate.

5 22. The pharmaceutical composition as defined in Claim 20 further including an outer protective coating surrounding said bilayered tablet.

23. The pharmaceutical composition as defined in Claim 1 further including an antioxidant.

10 24. The pharmaceutical composition as defined in Claim 23 wherein the antioxidant is vitamin C and/or vitamin E.

15 25. A method for lowering serum cholesterol or preventing or inhibiting or treating atherosclerosis or reducing risk of or treating a cardiovascular event or disease, coronary artery disease or cerebrovascular disease, which comprises administering to a patient in need of treatment a therapeutically effective amount of a pharmaceutical composition comprising a combination of a statin cholesterol lowering agent and aspirin in a single dosage form, which dosage form minimizes interaction between the statin and aspirin, and reduces the side effects of aspirin.

20 26. The method as defined in Claim 25 wherein the statin employed is pravastatin, lovastatin, simvastatin, atorvastatin, fluvastatin or cerivastatin.

add A2
add B1